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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,214	08/29/2006	Tomoyuki Hasegawa	Q92149	2252

23373 7590 01/22/2010

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
MOORE, SUSANNA	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
01/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/561,214	HASEGAWA ET AL.	
	Examiner	Art Unit	
	SUSANNA MOORE	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-9 and 24* is/are rejected.

7)☒ Claim(s) *3-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/2009 has been entered.

Response to Amendment

Applicant's arguments, see Remarks, filed 3/16/2009, with respect to Office Action mailed 11/25/2008 have been fully considered. Some of the rejections have been withdrawn, others have been maintained, and some are new rejections or are new as a result of Applicant's amendments. Thus, this is a Final Office Action. In summary, claims 1-9 and 24 are currently pending and under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/9/2009, was filed with and RCE on 11/25/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The DSs have the same references cited and thus only one was considered.

Specification

The objection of the disclosure is objected to because of the following informalities: a substitute specification is required pursuant to 37 CFR 1.125(a) because the instant specification is not grammatically correct is **withdrawn** based on the amendments.

The substitute specification filed 11/9/2006 has been entered because it does conform to 37 CFR 1.125(b).

Claim Objections

The objection of claims 1, 12 and 20 because of the following informalities: the term "Corticotropin Releasing Factor" is **withdrawn** based on the amendments.

The objection of claim 5 because of the following informalities: the claim is missing a period at the end of the claim is **withdrawn** based on the amendments.

Claims 3-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The rejection of claims 11, 20 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite is **withdrawn** based on the amendments.

The rejection of the phrase "a disease resulting from elevated activity of Corticotropin eleasing Factor" is indefinite is **withdrawn** based on the amendments.

The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for the phrase, "which is superior in thermal stability," is **withdrawn** based on the amendments.

The rejection of claim 20 for being vague and indefinite in that the claim provided for the use of claimed compounds is **withdrawn** based on the amendments.

The rejection of claims 11-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** based on the amendments.

Claim Rejections - 35 USC § 103

The rejection of claims 1-9,11-15, 20 and 24 under 35 U.S.C. 103(a) as being unpatentable over Nakai et. al. (WO 2002/053565, US equivalent 7034153 B2) is **withdrawn** since the WO nor the US document qualify as a 102(e) reference. The instant Application is entitled to the 6/25/2003 foreign priority date.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 8, 9 and 24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7034153. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons provided below.

The instant Application is claiming 8-(3-Pentylamino)-2-methyl-3-(2-chloro-4-methoxyphenyl)-6,7-dihydro-5H-cyclopenta[d]pyrazolo[1,5-a]pyrimidine methanesulfonate, simple compositions, a method of making the methanesulfonate salt and a method of antagonizing the CRF receptor with said salt.

Nakai et. al. is claiming 8-(3-Pentylamino)-2-methyl-3-(2-chloro-4-methoxyphenyl)-6,7-dihydro-5H-cyclopenta[d]pyrazolo[1,5-a]pyrimidine and pharmaceuticall acceptable salts thereof, see claim 1, column 253. The hydrochloride salt is taught in column 77, lines 1-33. The methanesulfonate salt is taught in column 22, line 9. Nakai also teaches the intended use, see column 2, line 7. It is routine experimentation to make a methansulfonate salt of an amine compound. Furthermore, if the compound is obvious the method of making said compound is obvious. The fact that the crystalline property is being claimed of 8-(3-Pentylamino)-2-methyl-3-(2-chloro-4-methoxyphenyl)-6,7-dihydro-5H-cyclopenta[d]pyrazolo[1,5-a]pyrimidine methanesulfonate, simple compositions, a method of making the methanesulfonate salt does not

overcome the obviousness between the reference and the instant Application. If the crystalline form of any compound is introduced into a pharmaceutically acceptable carrier, which is a liquid, the crystallinity of the compound is lost. Thus, said claims are rendered obvious by Nakai et. al.

An argument was used from a previous 103 rejection from the office action dated 2/25/2009 was applied. Applicant traversed the above rejection by stating, "As described in the instant specification (page 5, lines 1-11), Applicants note that there are potential problems, e.g., inferior stability, low yield, associated with 8-(3-Pentylamino)-2- methyl-3-(2-chloro-4-methoxyphenyl)-6,7-dihydro-5H cyclopenta[d]pyrazolo[1,5-a]pyrimidine hydrochloride. On the other hand, the claimed compound (i.e., methanesulfonate salt form) exhibits unexpectedly superior thermal stability over the hydrochloride salt form (page 11, lines 10-25). Additionally, Applicants also note that the effect is specific to the methanesulfonate salt because the thermal stability cannot be obtained by other pharmaceutically acceptable salts. For example, phosphoric acid salt of 8-(3-Pentylamino)-2-methyl-3-(2-chloro'4-methoxyphenyl)- 6,7.dihydro-5H-cyclopenta[d]pyrazolo[1,5-a]pyrimidine has endothermic and exothermic peaks and has a problem in thermal stability. In this respect, it is surprising that one salt form can provide such a big effect on thermal stability. In view of foregoing, Applicants submit that the present invention is not obvious over Nakai et al."

This is not found persuasive. These results are not unexpected. It is known in the art that mesylate salts produce higher melting point compounds, see Bastin et. al. (Organic Process & Development, 2000, 4, pages 427-435). On page 431, the RPR 127963 compound was produced in five crystalline salts, i.e. hydrochloride, mesylate, citrate, tartrate and sulfate, see first full paragraph in the left-hand column. Also note in the right-hand column, first full paragraph where

the mesylate and sulfate salts of said compound are described as having high melting points. Moreover, the mesylate salt is one of the most popular anionic salts which is FDA approved commercially, see Berge et. al. (Journal of Pharmaceutical Sciences, 1977, pages 1-19), see page 2, Table 1, right hand side. One of ordinary skill in the art would make the mesylate salt based on the Berge reference and expect a higher melting point compound, based on the Bastin reference. Thus, the rejection is **maintained**.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/

Examiner, Art Unit 1624